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09/728,911	12/01/2000	Scott R Presnell	99-93	2372

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EXAMINER

ROARK, JESSICA H

ART UNIT

PAPER NUMBER

1644

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12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/728,911

Applicant(s)

PRESNELL ET AL.

Examiner

Jessica H. Roark

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 December 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3,8-42 and 47-71 is/are pending in the application.
- 4a) Of the above claim(s) 8-18,21-42,54-66 and 71 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3,19,20,47-53 and 67-70 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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DETAILED ACTION

1. Claims 1-3, 8-42 and 47-71 are pending.

2. Applicant's election without traverse of Group I with a species election of a homodimeric receptor complex in Paper No. 11 is acknowledged.

Claims 8-18, 21-42, 54-66 and 71 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Claims 1-3, 19-20, 47-53 and 67-70 are under consideration in the instant application.

Priority

3. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged.

Provisional applications 60/232,219 and 60/244,610 appear to provide adequate written support for instant claims 1-3, 19-20, 47-53, and 67-70.

However, provisional application 60/169,049 (filed 12/3/1999) upon which priority is claimed does not appear to provide adequate support under 35 U.S.C. 112 for claims 47-53 and 68-70 of this application with respect to limitations regarding the nature of the receptor complex (homodimeric, heterodimeric, etc.).

Applicant is invited to point to adequate written support for these claims in the provisional applications.

IDS

4. It is noted that no IDS appears to have been filed in the instant case.

Specification

5. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which Applicant may become aware in the specification.

6. The disclosure is objected to because it contains an embedded hyperlink at least on page 166 at line 22. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Applicant is requested to review the application for additional embedded hyperlinks and/or other forms of browser-executable code and delete them. Embedded hyperlinks and/or other form of browser-executable code are impermissible in the text of the application as they represent an improper incorporation by reference. See MPEP § 608.01 and 608.01(p).

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Claim Objections

7. Claims 1-3 are objected to because of the following informalities: in subsection (a) of each claim, "amino acid residues" appears as duplicate text. Appropriate correction is required.

Claim Rejections - 35 USC § 112 second paragraph

8. The following is a quotation of the second paragraph of 35 U.S.C. 112.

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-3 and 19-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claim 1 is ambiguous and fails to set forth the metes and bounds of the claims because it is unclear from the instant claim language if Applicant intends the claim to be limited to a polypeptide as set forth in subsections (a) - (g) (i.e., if the polypeptide comprising at least 15 contiguous amino acid residues of an amino acid sequence of SEQ ID NO:2 is either (a) or (b) or (c), etc.); or if the claim is intended to encompass any polypeptide comprising at least 15 contiguous amino acid residues, wherein the 15 contiguous amino acid residues are contained within a sequence as set forth in (a) or (b) or (c), etc.

The first interpretation results in "closed" claim language (i.e., the claim is limited to an explicit sequence), the second interpretation results in "open" claim language, encompassing any polypeptide comprising 15 contiguous amino acids from within one of the fragments of SEQ ID NO:2.

For examination purposes, claim 1 will be interpreted as "open".

B) Claims 2-3 and 19-20 are indefinite in that they recite amino acid residues without providing a reference SEQ ID NO:.

For examination purposes, claim 2 will be interpreted as reciting "An isolated polypeptide that comprises an amino acid sequence of SEQ ID NO:2 selected from the group consisting of:...".

C) Applicant is reminded that any amendment must point to a basis in the specification so as not to add new matter. See MPEP 714.02 and 2163.06.

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Claim Rejections - 35 USC § 112 first paragraph

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 50, 67 and 69 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The specification as originally filed does not provide support for the invention as now claimed. *This is a New Matter rejection for the following reasons:*

Applicant's amendment asserts that no New Matter has been added. However, the specification does not appear to provide an adequate written description of "a *polypeptide or receptor complex* that further comprises a biotin/avidin label, a radionuclide, an enzyme, a substrate, a cofactor, an inhibitor, a fluorescent marker, a chemiluminescent marker, or a cytotoxic molecule".

While it is acknowledged that these limitations do appear in the specification (e.g., on page 95), the Examiner was only able to identify support for an antibody, not the polypeptide or receptor complex, "further comprising".

The instant claims now recite limitations which were not clearly disclosed in the specification and claims as filed, and now change the scope of the instant disclosure as filed. Such limitations recited in the present claims, which did not appear in the specification or original claims, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Applicant is required to cancel the New Matter in the response to this Office Action.

Alternatively, Applicant is invited to clearly point out the written support for the instant limitations.

12. Claims 1-2, 47-53 and 67-69 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The following *written description* rejection is set forth herein.

The claims recite an "isolated polypeptide comprising a fragment" as part of the invention.

As noted supra, claim 2 does not recite any particular SEQ ID NO. However, for examination purposes the claim is considered with respect to SEQ ID NO:2.

The claims are drawn to a large genus of polypeptides sharing one of the core sequences set forth in subsections (a)-(g) of the claim. Fragment language that encompasses open (comprising) claim language permits an unlimited number of unidentified flanking sequences to be added to the recited subsequence. Thus there is substantial variation permitted within a genus of polypeptides comprising each of the various fragments (of SEQ ID NO:2) and no requirement that these polypeptides share any function.

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The Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement make clear that the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, see especially page 1106 3rd column).

A "representative number of species" means that the species which are adequately described are representative of the entire genus. Thus, when there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus. (See MPEP 2163 II. ii).

In the instant case Applicant has described only SEQ ID NO:2 and a polypeptide comprising a particular fragment of SEQ ID NO:2, the fragment of SEQ ID NO:2 from 22-231 (instant SEQ ID NO:13). SEQ ID NO:2 from 22-231 is the fragment used in the zcytoR16sFc4 fusion protein construct, e.g., in Example 10 on pages 143-144 and Examples 15-16 on pages 156-159. The specification further discloses in Examples that this fragment binds the cytokine IL-TIF, also known as IL-22 (Example 10 at pages 143-144), and that this fragment is a functional antagonist of IL-TIF (Examples 15-16 on pages 156-159).

The disclosed polypeptide comprising SEQ ID NO:2 from 22-231 does not, however, appear to be a representative species of a genus of polypeptides comprising other fragments of SEQ ID NO:2 because it is not representative of the variation present within any genus comprising the other recited fragments, and because there is no requirement that the other polypeptides comprising share the function of binding IL-TIF (SEQ ID NO:15).

Thus the specification does not allow one skilled in the art to visualize or recognize the identity of the subject matter purportedly described. Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the written description inquiry, whatever is now claimed." (id at 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (id at 1116.).

Consequently, Applicant was not in possession of the instant claimed invention. See Regents of the University of California v. Eli Lilly and Co. 43 USPQ2d 1398.

Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Applicant is invited to point to clear support or specific examples of the claimed invention in the specification as-filed.

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13. Claims 1-2, 47-53 and 67-70 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a polypeptide, or for a receptor complex comprising a polypeptide, that

- a) comprises the amino acid sequence set forth in SEQ ID NO:2,
- b) comprises amino acid residues 22 to 231, or 21-231, of SEQ ID NO:2 wherein the polypeptide binds IL-TIF (SEQ ID NO:15), or
- c) consists of SEQ ID NO:2 or internal fragments of SEQ ID NO:2;

does not reasonably provide enablement for a polypeptide or for a receptor complex comprising that

- a) comprises fragments of SEQ ID NO:2 that does not bind IL-TIF (SEQ ID NO:15), or
- b) comprises a fragment of SEQ ID NO:2 smaller than residues 22-231 of SEQ ID NO:2.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

As noted supra, claim 2 does not recite any particular SEQ ID NO. However, for examination purposes the claim is considered with respect to SEQ ID NO:2.

The specification discloses the polypeptide of SEQ ID NO:2, and that a fusion protein comprising the amino acid sequence of SEQ ID NO:2 from 22-231 has the function of binding the cytokine IL-TIF (SEQ ID NO:15, also known as IL-22) and antagonizing the function of IL-TIF (e.g., Example 10 on pages 143-144 and Examples 15-16 on pages 156-159).

The instant claims recite in various forms polypeptides comprising "fragments" of a certain number of amino acid residues of SEQ ID NO:2. "Comprising" language opens the claim up to the inclusion of additional residues of undisclosed identity and number flanking the recited "fragment". The skilled artisan can make fragments *limited* to *subsequences* of SEQ ID NO:2 without undue experimentation. However, before the skilled artisan can make polypeptides *comprising* "fragments" with additional flanking sequence, guidance is required with respect to the identity of those flanking sequences. In the instant case however, the specification does not appear to provide this needed guidance in a manner commensurate in scope with the large number of polypeptides comprising fragments of SEQ ID NO:2 encompassed by the instant claim language.

In addition, there is no requirement that any of these polypeptides comprising fragments share with SEQ ID NO:2 or the fragment of SEQ ID NO:2 from 22-231 the function of binding IL-TIF (except claim 70). Thus the scope of the instant claims encompass any polypeptide which comprises the recited fragments, irrespective of the function of that polypeptide. A skilled artisan would not know how to use these many other polypeptides comprising fragments commensurate in scope with the limited guidance provided in the specification.

It is unpredictable which fragments of SEQ ID NO:2 provide a minimal sequence necessary for IL-TIF binding. Although the specification discloses that amino acids 22-231 of SEQ ID NO:2 can convey the function of IL-TIF binding to an Fc fusion protein comprising the sequence, there appears to be insufficient guidance in the specification as to the minimal structure that convey this function.

Dumoutier et al. (J. Immunol. June 15, 2001; 166:7090-7095) teach that there is a longer splice variant of SEQ ID NO:2 (SEQ ID NO:2 is called IL-22BP by Dumoutier et al.) which has an insertion of 96 nucleotides in the coding region and that this form is less efficiently secreted and fails to block IL-22 activity (see e.g., page 7094, first full paragraph).

Further, the skilled artisan would not expect that fragments smaller than amino acids 22-231 of SEQ ID NO:2 would possess this activity because the skilled artisan was aware that the soluble receptors, such as the instant SEQ ID NO:2, were of such small size as to preclude more extensive deletions without affecting function.

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For example, Kotenko et al. (J. Immunol. June 15, 2001; 166:7096-7103) teach that there is a shorter splice variant of SEQ ID NO:2 (SEQ ID NO:2 is called IL-22BP by Kotenko et al.) that they suggest is not likely to bind IL-22 (see e.g. page 7102, next to last paragraph). It is also noted that the smaller fragments of 22 to 108, 112-210 and 21-110 only encompass some of the structurally important cysteines of the full length sequence; therefore the skilled artisan would consider it unpredictable as to whether these fragments would retain enough of the structure of SEQ ID NO:2 to provide the IL-TIF binding function. Claim 70 is included in this rejection because for the reasons set forth supra it is unpredictable that the 22-210 subsequence of SEQ ID NO:2 is sufficient to provide the function of IL-TIF binding.

Reasonable correlation must exist between the scope of the claims and scope of enablement set forth. Without sufficient guidance, it would require undue experimentation of the skilled artisan to make polypeptides comprising fragments of SEQ ID NO:2 that could be used to bind IL-TIF; thus the experimentation left to those skilled in the art, is unnecessarily, and improperly, extensive and undue.

Applicant is invited to provide objective evidence that any of the other fragments of SEQ ID NO:2 would provide the function of binding IL-TIF, and to require that polypeptides comprising IL-TIF binding fragments retain the IL-TIF-binding function.

35 U.S.C. § 102

14. The following rejection under 35 U.S.C. § 102 is made under the assumption that the effective filing date for claims 47-53 and 68-70 is 9/13/2000, which is the filing date of provisional application 60/232,219.

Claim Rejections – 35 U.S.C. § 102

15. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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16. Claims 47-50 are rejected under 35 U.S.C. 102(e) as being anticipated by Agarwal et al. (WO 01/98342, see pages 1-33, 71-75, 81 and SEQ ID NOS:18-20 and 40-42).

Agarwal et al. teach the isolated sbg456548CytoRa polypeptide set forth in SEQ ID NO:41 (see especially SEQ ID NO:41, Table I on page 24, Table II on page 27, Table III on page 31 and Table IV on pages 71-75). Agarwal et al. teach that the sbg456548CytoRa polypeptide set forth in SEQ ID NO:41 is a cytokine receptor (e.g., Table III on page 31). Agarwal et al. teach that the polypeptide may be labeled, e.g., with a radioactive isotope or chemically modified (e.g., page 16).

The sbg456548CytoRa polypeptide set forth in SEQ ID NO:41 is identical to instant SEQ ID NO:2, and is therefore an isolated soluble cytokine receptor polypeptide comprising a sequence of amino acids as shown in SEQ ID NO:2 from amino acid 22-231 or 22-210.

While the recitation regarding formation of a homodimeric, heterodimeric, or multimeric receptor complex is noted, these limitations appear to refer to inherent properties of a polypeptide comprising amino acid residues 22-231 or 22-210 of SEQ ID NO:2 since the preamble does not recite a complex.

Applicant is reminded that no more of the reference is required than that it sets forth the substance of the invention. The claimed functional limitations would be inherent properties of the sbg456548CytoRa polypeptide set forth in SEQ ID NO:41 of Agarwal et al.

The reference teachings thus anticipate the instant claimed invention.

Conclusion

17. No claim is allowed.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica Roark, whose telephone number is (703) 605-1209. The examiner can normally be reached Monday to Friday from 8:00 to 4:30. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached at (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

Jessica Roark, Ph.D.
Patent Examiner
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March 24, 2003

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